

REMARKS

Claim 1 has been amended and claims 15-17 are cancelled.

The Examiner asserts that the present invention is obvious over US2005/0181052(D1) in view of USP 6,887,307(D2). However, the present invention is not obvious over D1 and D2.

Capsules used widely in pharmaceutical preparations are gelatin capsules or HPMC capsules. On the other hand, pullulan capsules are not generally used for the reasons that there are not many manufacturers of pullulan capsules and the pullulan capsule was developed only recently (pullulan itself is used in the food and pharmaceutical industries for more than 25 years (see paragraph 2 in the attached document (product information of NPcaps Capsule))).

Therefore, when a capsule other than a gelatin capsule is used, those skilled in the art will naturally select HPMC capsules known to be safe and useful. Under the circumstances, the inventors daringly selected a pullulan capsule and confirmed the stability of the pullulan capsule to reach the present invention.

Additionally, the amended claimed invention contains at least two solid preparations having different medicine release properties. Therefore, the present invention in which the combined solid preparations having different medicine release properties are encapsulated into the pullulan capsule is not obvious over D1 and 2.

Favorable consideration and allowance is solicited.

Respectfully submitted,

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April 4, 2011



PRODUCTS

NPcaps® Capsules

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NPcaps® capsules are an all-natural, two-piece non-animal capsule suitable for addressing a variety of cultural and dietary requirements, including those of vegetarians, diabetics and patients with restricted diets.

NPcaps capsules are made from pululan, a water-soluble polysaccharide produced through a fermentation process. Widely used in Japan, pululan is very stable and well-characterized, and has achieved broad regulatory acceptance around the world with its proven safety record. It has been in commercial production for more than 25 years, having numerous uses in the food and pharmaceutical industries.

The natural balance between health and technology

With the trend moving towards healthier lifestyles, consumers are becoming more and more selective. That's why Capsugel is one step ahead of the development curve with NPcaps pululan capsules, a highly effective encapsulation option that helps differentiate your product in a 100% natural, crystal-clear capsule material.

NPcaps pululan capsules are odorless, tasteless, and completely biodegradable two-piece capsules made from this completely natural, vegetable-derived polysaccharide. Because pululan capsules are impermeable to oxygen transmission, NPcaps capsules are recommended for encapsulating oxidation-sensitive ingredients to provide enhanced protection.

NPcaps pululan capsules feature unique characteristics for an all-natural capsule alternative:

100% natural

- Vegetable origin
- No chemical modification
- Non-GMO Pululan
- Starch-free
- Preservative-free
- Gluten-free

Elegant appearance

- Crystal-clear transparency
- Glossy finish

Ideal capsule for oxidation-sensitive ingredients

- Enhanced protection of capsule ingredients
- May extend shelf life
- Less need for anti-oxidants

Excellent machinability

- NPcaps capsule dimensions are identical to our Coni-Snap® capsules
- Machinability tests were successfully conducted with various CFM manufacturers

Proven commercial viability

- Over 120 customers
- More than 3 billion NPcaps capsules sold
- Over 100 products encapsulated in NPcaps capsules

As with all Capsugel products, you can be assured of the highest quality product and technical service. NPcaps pululan capsules are manufactured in a GMP facility that meets ISO 9000 certification criteria. Computerized process control stations monitor key manufacturing process parameters, and a certificate of analysis is included in every production batch.

For more information about NPcaps® capsules, contact a Capsugel Representative.

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